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NM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/978,632 11/25/97 RABBANI

E ENZ-53(C)

HM22/1108

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527 MADISON AVENUE
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NEW YORK NY 10022

EXAMINER

SCHMIDT, M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED:

11/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/978,632

Applicant(s)

Rabhani et al

Examiner

Schmidt

Group Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/6/99
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-24 and 245 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-24 and 245 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1635

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-24 and 245 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the Official action mailed 02/03/99.

Applicant's arguments filed 08/06/99 have been fully considered but they are not persuasive.

Claim 1 was amended to claim "a non-native polynucleotide construct comprising at least one sequence segment, which construct when present in a cell produces a product, said construct comprising at least one member selected from the group consisting of a modified nucleotide, a nucleotide analog or a non-nucleic acid entity, and a combination of the foregoing." Claim 1 as amended continues to read on a multitude of possible nucleic acid constructs for use in a cell to produce a product as recited in the previous Official action mailed 02/03/99. The "non-native" language of instant claim 1 reads on a broad scope of any nucleic acid construct which was not

Art Unit: 1635

native to the host cell recipient, ie. any nucleic acid construct transformed, transfected, etc. into a host cell. The breadth of constructs encompassed by the instant claims reads on any non-native single, double or triple stranded nucleic acid containing construct as well as any vector construct which produces a product in a cell, and further reads on applications to whole organisms. As was argued in the first Official action on the merits, the instant claims read on a multitude of constructs for application in a cell or whole organism, including for instance application of antisense constructs to a cell, but the specification as filed is not enabling for the breadth of constructs claimed.

The specification as filed taught prophetically how to make and use a variety of nucleic acid constructs and taught by way of example a vector construct for administration of antisense molecules to cells in culture. The specification as filed however did not teach production of a product in a cell other than administration of the antisense construct, and therefore did not teach by way of example administration to a cell of any nucleic acid construct having a nucleic acid modification as claimed in instant claim 1 since the antisense construct taught had no such nucleic acid modifications. It was then argued that the constructs taught either prophetically or by way of example which read on expressing an antisense construct in vitro, would not be enabled for application to a whole organism because of the unpredictability in the antisense art for whole organism administration of such constructs.

Since, applicant made no attempt to refute the unpredictability of administration of antisense expressing constructs to whole organisms. On page 9 of the Amendment filed 08/06/99,

Art Unit: 1635

applicant merely states that "the state of the art of construct technology in biological systems at the time this application was originally filed in 1995 had become predictable enough so that the skilled artisan could have practiced Applicants' claimed invention, again, without any undue experimentation." However, no remarks were made concerning the factors considered unpredictable for whole organism application of the instantly claimed constructs considering the lack of teaching in the specification and the art for constructs encompassed by the breadth of the claimed invention having the claimed functionality of producing a product in a cell in a whole organism. The claims as amended thus remain rejected for lack of teaching in the specification as filed for one skilled in the art to make and/or use the instantly claimed constructs.

3. Claims 1-24 and 245 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official action mailed 02/03/99.

Applicant's arguments filed 08/06/99 have been fully considered but they are not persuasive. Applicant did not address the arguments presented in the Official action mailed 02/03/99 that one skilled in the art was not in possession of the multitude of possible nucleic acid constructs instantly claimed. The amendment of claim 1 to comprise "non-native" polynucleotides does appear to more clearly define the metes and bounds of possible constructs to

Art Unit: 1635

any nucleic acid construct not formerly present in the host cell which produces the product. However, the amendment does not more clearly describe the genus of possible structures for the breadth of possible single stranded, double stranded, triple stranded, or circular (ie. vector-like) constructs contemplated by the instant claims as written since the breadth of such constructs is not adequately represented by the figures taught in the specification as filed as argued previously.

Claim Rejections - 35 USC § 102

4. Claims 1-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Meyer et al., for the reasons of record set forth in the Official action mailed 02/03/99.

Applicant's arguments filed 08/06/99 have been fully considered but they are not persuasive.

Applicant states that "Meyer's patent neither discloses nor suggests Applicants' claimed invention." However, Meyer specifically teaches application of a non-native polynucleotide construct to a cell which produces a product and comprises modifications as instantly claimed.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1635

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

M. M. Schmidt
November 5, 1999



George C. Elliott, Ph.D.
Supervisory Patent Examiner
Technology Center 1600